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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/622,146 01/02/01 BARBUCCI

R 515-4204

EXAMINER

IM22/0403

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ART UNIT

PAPER NUMBER

1711

DATE MAILED:

04/03/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/622,146

Applicant(s)
Barbucci et al.

Examiner
Rabon Sergeant

Group Art Unit
1711



- ☐ Responsive to communication(s) filed on _____.
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 1-19 is/are pending in the application.
- Of the above, claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1-19 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claims _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) _____.
- ☒ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☒ Notice of References Cited, PTO-892
- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 1
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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1. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.
2. The incorporation of essential material in the specification by reference to a foreign application or patent, or to a publication is improper. Applicant is required to amend the disclosure to include the material incorporated by reference. The amendment must be accompanied by an affidavit or declaration executed by the applicant, or a practitioner representing the applicant, stating that the amendatory material consists of the same material incorporated by reference in the referencing application. See *In re Hawkins*, 486 F.2d 569, 179 USPQ 157 (CCPA 1973); *In re Hawkins*, 486 F.2d 579, 179 USPQ 163 (CCPA 1973); and *In re Hawkins*, 486 F.2d 577, 179 USPQ 167 (CCPA 1973).
3. The attempt to incorporate subject matter into this application by reference to WO 95/25751 and WO 98/45335 is improper because the descriptions of the hyaluronic acid or derivatives constitutes essential material.
4. Claims 1-19 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants have failed to provide adequate description pertaining to the hyaluronic acid and what constitutes derivatives of hyaluronic acid.

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5. Claims 1-19 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicants have failed to provide adequate enablement with respect to the hyaluronic acid or derivatives.

Furthermore, with respect to claim 19, applicants have failed to teach how to use the polymer to produce artificial kidneys, hearts, pancreas, and livers.

6. Claims 2-8, 12-17, and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Within claim 2, the language, "the starting polyurethane", lacks antecedent basis.

Within claim 3, "the starting sulphated hyaluronic acid" lacks antecedent basis.

Within claim 4, "the starting sulphated hyaluronic acid derivative" lacks antecedent basis.

Within claim 5, "the starting sulphated hyaluronic acid" lacks antecedent basis.

Furthermore, claim 4 is directed to derivatives, not acids. Within line 6, aliphatic is spelled incorrectly. Within lines 6 and 12, it is not clear what "series" refers to or what compounds are actually encompassed by the series. Within line 12, it is unclear what constitutes "spacer chains". Within line 9, it is unclear what "the same hyaluronic acid" refers to. Is it intended to refer to the same acid molecule?

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Within claim 6, it is unclear if the residue of the acid or derivative or if the acid or residue, itself, contains at least one carboxylic function. In other words, are formulas (I) and (II) required to be acid functional.

Within claim 7, "formula (I)", "the polyurethane (IV)", "formula (III)", "HOOC-Hsulph", and "the adduct (III)" either lack definition or antecedence.

Within claim 8, "formula (II)", "HOOC-Hsulph", "the adduct of formula (VI)", "the adduct (VI)", "the polyurethane (IV)", and "product (II)" either lack definition or antecedence. Also, it is unclear how "desired" further defines "product (II)".

Within claim 12, it is unclear what constitutes "their fragments" with respect to proteins.

Within claims 13 and 15, it is unclear what constitutes "a semisynthetic polymer".

Within claims 14, 15, and 19, the use of "such as" and the language denoted by "such as" renders the claims indefinite, because it is unclear if or to what extent the species language is to modify the generic language.

Within claim 15, it is unclear what constitutes "precursors of the same".

Within claim 16, it is unclear what constitutes, "copolymers of the same or their derivatives".

Within claim 17, the species should be referred to in the alternative.

Within claim 19, it is unclear what constitutes "soft tissue prostheses" or "protheses of animal origin".

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7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 1-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Balazs et al ('865) in view of WO 95/25751 and Halpern et al ('114).

Balazs et al disclose the covalent bonding of hyaluronic acid to polyurethane and the use of such materials in medical applications. See example 3.

9. Balazs et al are silent regarding the sulphate modification of the hyaluronic acid component; however, sulphated hyaluronic acids and their use with polyurethanes and their use within medical applications was known in the art at the time of invention. This position is supported by the teachings of WO 95/25751. See entire document and especially line 20 of page 28. Furthermore, the covalent bonding of polysaccharides, including sulphate containing

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polysaccharides, to substrates, including isocyanate group containing substrates, to produce medical articles was known at the time of invention. See abstract; figures; and column 4, lines 20+ within Halpern et al.

10. In view of the teachings within Halpern et al. regarding the bonding of sulphate polysaccharides to isocyanate containing substrates, the position is taken that it would have been obvious to utilize the sulphated hyaluronic acids of WO 95/25751 as the hyaluronic acid component of Balazs et al. so as to arrive at the instant invention.

Any inquiry concerning this communication should be directed to R. Sergent at telephone number (703) 308-2982.

Sergent/nt

3-31-01


RABON SERGENT
PRIMARY EXAMINER